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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/554,956 07/11/00 BADLEY

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000909
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HM22/0703

EXAMINER

GABEL, G

ART UNIT

PAPER NUMBER

1641

DATE MAILED:

07/03/01

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/554,956

Applicant(s)

BADLEY ET AL.

Examiner

Gailene R. Gabel

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-16 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-16, and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed 4/30/01 in Paper No. 9 is acknowledged and has been entered. Claims 4 and 17-19 have been cancelled. Claims 1, 7, 8, and 18 have been amended. Claim 22 has been added. Accordingly, claims 1-3, 5-16, and 22 are pending and under examination.

Claim Objections

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 22 has been renumbered 20. Accordingly, claims 1-3, 5-16, and 20 are pending and under examination.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 1-3, 5-16, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 lacks antecedent support in reciting "**the** displaceable moiety for the analyte".

Claim 12 remains unclear in reciting "properties". The term "properties" renders the claim indefinite because the claim includes elements not actually disclosed (those encompassed by "properties"), thereby rendering the scope of the claim unascertainable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The rejection of claim 4 is now moot in light of Applicant's cancellation of the claim.

5. Claims 1-3, 7-10, and 13-16 stand rejected under 35 U.S.C. 102(b) as being anticipated by Schramm et al. (WO 91/05262) for reason of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 5-6, 11-12, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schramm et al. (WO 91/05262) in view of Tom-Moy et I. (EP 0 416 730) for reason of record.

Note: Claims 1-3, 7-10, and 13-16 have been previously rejected under 35 U.S.C. 102(b) as being anticipated by Schramm et al. (WO 91/05262) for reason of record.

7. Claims 1-16 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garland et al. (WO 92/18867) in view of Tom-Moy et I. (EP 0 416 730) for reason of record.

Response to Arguments

8. Applicant's arguments filed 4/30/01 have been fully considered but they are not persuasive.

a) Applicant argues that Schramm et al. does not disclose the method taught by the instant invention because the fluorescent or enzyme labels taught by Schramm et al. are inherently capable of providing assay signal regardless of where the displaceable moiety is located whereas the in instant invention the assay signal can only be generated when the displaceable moiety has been captured at the second surface.

In response, the rejected claims as currently recited (open language) do not exclude other reagents or steps and further do not exclude that the fluorescent or enzyme labels provide the signal regardless of where the displaceable moiety is located within the assay.

b) Applicant argues that the combination of Schramm et al. and Tom-Moy et al. is not obvious and there was no motivation provided / taught by either reference to combine them. Applicant argues that Tom-Moy only discloses a single measurement surface, cannot be used to provide a different signal at different locations, and does not disclose use of labeled displaceable moiety.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Tom-Moy et al. disclose assays for detecting binding of ligands and detecting by generation of modulation of an evanescent or acoustic wave. According to Tom-Moy et al. the device has a surface with overlaying layers composed of ligand binding substances and ligand conjugated compounds wherein the latter has a binding affinity toward the analyte of interest upon binding of a sample. One of ordinary skill in the art at the time of the instant invention would have been motivated to incorporate the detection method of Tom-Moy into the assay taught by Schramm because Tom-Moy specifically provided the advantage of using acoustic wave detection by the mass biosensor by reducing non specific binding especially in detecting trace quantities of analyte in a sample.

c) Applicant argues that Garland et al. does not disclose the method taught by the instant invention wherein the displaceable moiety is displaced by analyte in an affinity related manner. Further, Applicant argues that SPR is an essential feature for detection in the assay of Garland et al. which is not suggested by Tom-Moy et al.

In response, the rejected claims as currently recited (open language) do not exclude displaceable moieties that are displaced by analyte in an affinity related manner such as in the method of Garland et al.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case,

Tom-Moy et al. disclose assays for detecting binding of ligands and detecting by generation of modulation of an evanescent or acoustic wave. According to Tom-Moy et al. the device has a surface with overlaying layers composed of ligand binding substances and ligand conjugated compounds wherein the latter has a binding affinity toward the analyte of interest upon binding of a sample. One of ordinary skill in the art at the time of the instant invention would have been motivated to substitute the detection method of Tom-Moy into the assay taught by Garland because Tom-Moy specifically provided the advantage of using acoustic wave detection by the mass biosensor by reducing non specific binding especially in detecting trace quantities of analyte in a sample.

9. No claims are allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

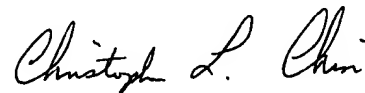
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday-Thursday from 6:30 AM - 4:00 PM and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 308-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Gailene R. Gabel
June 30, 2001



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800 / 691